Washington State DOT

FTA Drug & Alcohol Program
Service Provider Assessment

Presented By Precision Compliance, Inc.

Resources

- Service Vendors Collection Sites
 - 49 CFR Part 40
 - » Specimen collection procedures
 - » http://www.dot.gov/ost/dapc/testingpubs/20040505_urine -wkbook1_01.pdf
- Service Vendors SAP
 - 40 CFR Part 40 Subpart O
 - SAP Guidelines
 - » http://transitsafety.volpe.dot.gov/Publications/substance/SAGuideLin es/PDF/SAPGuide.pdf

- Medical Review Officer
 - Part 40 Subpart G
- Breath Alcohol Technician
 - Part 40 Subparts J,K,L and M
- Collectors
 - Part 40 Subparts C,D, and E
- Third Party Administrator (c/TPA)
 - Part 40 Subpart Q
- SAMHSA Certified Laboratories
 - Part 40 Subpart F



"You're fired, Tack. The lab results just came back, and you tested positive for Coke."

Collection Site

- Develop a procedure for notifying site regarding employee's arrival time and information regarding notifying the DER
- Provide the new Part 40 regulations to your site.
- www.dot.gov/ost/dapc
 - Clean writing area
 - Privacy for urination
 - Toilet or void receptacle
 - Permanent or temporary
 - Hand washing area
 - Restricted area during testing

Collection Site (continued)

- Review prior to collection
 - All water sources turned off and bluing in the receptacle
 - Secure toilet tank top or use bluing
 - Ensure undetected access is not possible
 - No chemicals (soap, bleach etc) in the toilet area
 - Secure areas suitable for concealing contaminants
 - Donor instruction in specimen area
 - Secured area for specimens and collection procedures
- Certified collection employees
 - Check new qualifications, training and proficiency
- Use of correct Chain of Custody Form

Collection Site (continued)

- Only one collection at a time unless shy bladder wait period
- Keep sample in view of collector and employee until completion of the process
- Collector must maintain personal control over each specimen
- Collector must have contact information on the DER
- Perform the alcohol test before the drug test

How to audit your collection site

- □ Do you have coverage all hours of operation?
 □ Does the collection site use a consent form?
 □ Does the site check the donor's ID?
 □ Is there a procedure in effect if an employee is a "no show" or inappropriately late for an appointment?
 □ Does the site provide privacy?
- Die there restricted access to the area du
- ☐ Is there restricted access to the area during the collection procedure?

- Unwrap collection kit in front of donor
- Must produce at least 45ml urine
- Within 4 minutes check temperature of urine
- Visually examine specimen for tampering or adulteration
- Split specimen in two bottles, at least 30ml in one and 15ml in the second
- Seal and label both bottles, collector dates and donor initials
- Place containers in sealed shipping bag with proper chain of custody form in secured area

- Employer Mandatory observed collections no advanced notice to the employee
 - The Lab reported to the MRO an invalid specimen and there is no medical reason
 - The MRO reports the original positive, adulterated, or substituted result was cancelled due to the split being unavailable
 - You <u>may</u> require a Return to duty or follow-up test to be observed

- Collector Mandatory Observed Collections
 - Directed by the DER
 - Observed materials brought to the collection site
 - Employee's conduct clearly indicates a clear attempt to tamper or adulterate
 - Temperature on the original specimen was out of range
 - Original specimen appears to have been tampered with

- Observed Collections continued
 - Employee must be informed of the reason for the observed collection
 - Observation must be done by a person of the same gender
 - Keep policy consistent

How to audit your Collector

- ☐ Has the site received documented training?
- ☐ Does the site have a copy of the new regulations and is the collector familiar with them?
- ☐ Are the supplies readily available?
- ☐ Are the 5 part CCFs available?
- □ Does the collector inspect the voiding area prior to the collection
- ☐ Is there a procedure for contacting the DER?

How to audit your Collector

- ☐ Is the donor asked for a photo ID?
- ☐ Is the donor given instructions?
- ☐ Is the donor shown the instructions on the back of the CCF?
- □ Is the employee asked to wash his/her hands prior to giving a specimen?
- ☐ Is there a locked area for the donor's personal items
- □ Does the specimen stay in sight of the donor and collector until the process is finished and the samples are sealed?

How to audit your Collector

- ☐ Does the donor initial and collector date the bottle seal after it is placed on the specimen bottle?
- □ Does the collector understand the observed specimen collection protocols?
- □ Does the collector understand what to do if there is insufficient volume?
- □ Are the specimens kept in a secure location while waiting for the courier?

Laboratory Procedures

- Urinalysis for drugs
 - Split specimen
 - Federal Chain-of-Custody and Control Form
 - (5 part)
 - Initial Screen
 - Confirmation test
 - Validity testing

HHS Laboratory

- Must be HHS certified
- Validity testing determines if the specimen is consistent with normal human urine
 - Creatinine level
 - Specific gravity
 - pH
 - Adulterants
 - a substance not expected in human urine
 - a substance expected but is present at inappropriate levels
 - physical characteristics that are outside normal range
 - if unable to ID the adulterant, must be sent to different lab

- Invalid
 - Unidentified adulterant or unidentified interfering substance
 - Abnormal physical characteristics
 - Normally found substance but found at an abnormal concentration
 - Substance which prevents lab from completing or obtaining a valid test result

- Primary specimen
 - Initial screening (immunoassay)
 - Confirmation if positive by GC/MS
 - Approved by certifying scientist
 - Results transmitted to MRO same day
 - Quantitations upon request by MRO
 - Quantitations on opiate greater 15,000ng/ml
 - Storage of positive results for 1 year (minimum)

- Split specimen
 - Long term frozen storage for one year if primary test is positive
 - Split specimen is forwarded to other HHS laboratory when requested
 - Validity testing required
 - Testing for the presence only (not for cut off levels)

- Turnaround time to the MRO should be no longer than 48 hours for negative results and 72 for positive results
- Maintain records for 2 years unless request to maintain longer
- Must provide semi-annual statistical summaries to the employer*-unless there is less than 5 tests in a period

How to audit your Laboratory

- □ Is the Laboratory certified by Dept. of Health and Human Services?
- □Do you have a copy of the Federal Register with the latest list of certified labs?
- ☐ Is there a second lab arrangement in the event of a split sample test or the suspension of the primary lab?
- □Does the lab try to correct correctable flaws?

How to audit your Laboratory

☐ Does the lab conduct validity testing? □Creatinine level □Specific gravity **□**pH □ Adulterants ☐ If the lab can not identify an adulterant does it send the specimen to another certified lab? ☐ Does the lab transmit results the same day they are certified? □ Does the lab send bi-annual statistics?

Alcohol Testing Procedure

- Breath testing
 - Evidential Breath Testing device (EBT)
 - New BAT form (2/1/2002)
 - 0.02-0.039 removed from safety-sensitive for 8 hours or subsequent test reads below 0.02
 - 0.04 or greater is a positive alcohol test
 - must be referred to Substance Abuse Professional (SAP)

Alcohol Testing Procedure (continued)

- Saliva Screening Test
 - if positive reading must be confirmed with EBT 15 minutes minimum and not longer than 30 minutes
 - Direct Supervisors can not act as STTs or BATs
- BAT/STT training requirements
 - Basic information
 - Knowledgeable of 49 CFR part 40 and current DOT guidance.
 - Qualification training
 - Proficiency on the device
 - Responsibility for maintaining
 - Integrity of the testing process and equipment
 - Privacy and dignity of employees

BAT/STT Requirements

- Initial proficiency demonstration
 - Seven error free tests
 - Performance monitored
 - Monitor documents that the tests were error free
- Refresher training
 - Every five years
- Error correction training
 - Required if a mistake results in a cancelled test
 - Completed within 30 days of when notified
 - Training and proficiency demonstrated and documented by monitor
 - Conduct 3 consecutive error free mock collections

How to audit your BAT/STT

☐ Does the BAT/STT have a certificate? ☐ Have they shown proficiency on the device they are using? ☐ Is the alcohol test performed prior to a urine drug test? ☐ Is there a BAT available all hours of operation? ☐ Does the BAT know how to contact the DER? ☐ Are all confirmations performed by the BAT using an approved EBT? ☐ Is the donor's ID checked? Back up procedure?

How to audit your BAT/STT

- □ Is only one test done at a time?
 □ Is the new ATF being used?
 □ Does the BAT understand that a refusal by the donor to sign step 2 is a refusal to test?
 □ Does the BAT wait at least 15 minutes to do a confirmation and use a new mouthpiece (when necessary)
- ☐ Does the BAT understand procedures for insufficient volume of breath?
- ☐ Are there records of adherence to the QAP?
- ☐ Is the EBT stored in a secured location?

Consequences of Positive tests

- Positive test
 - Removed from Safety-Sensitive position
 - Referred to SAP
 - Disciplinary policy
- Refusal to test same as a positive
- Definition of a refusal?
 - Verbal or Physical refusal
 - Insufficient volume without medical explanation

Refusals (continued)

- Tampering or adulterating specimen
- Not reporting immediately for testing
- Leaving the scene of an accident prior to submitting a test, without just cause
- Not allowing an observed or monitored collection when required
- Not allowing a medical examination when required.

Medical Review Officer (MRO)

- Licensed physician with detail knowledge of substance abuse disorders and drug testing and 49 CFR part 40, MRO guidelines and agency regulations
 - Knowledgeable about adulterated and substituted specimens
 - Purpose to review, interpret and verify test results, of positive, adulterated or dilute test
 - Notify employee of confirmed positive test
 - Review employees medical history/medical records
 - Protects the employee
 - No conflict of interest

- Qualification training
 - Collection procedures
 - CCF, reporting and recordkeeping
 - Interpretation of drug and validity test results
 - Roles and responsibilities of the MRO
 - Interaction with other participants
 - Changes and updates, guidance, interpretations and policies affecting the performance of the MRO
 - Satisfactory completion of an examination administered by a nationally-recognized MRO certification entity

- Qualification training, continued
 - If currently practicing MRO has met requirements by 8/1/01, the MRO does not have to retake
 - If currently practicing MRO has not completed by 8/1/01, training must be completed by 1/31/03
 - New MROs that begin practice after 8/1/01 must have training before they perform MRO duties.
- Continuing education
 - Every three years (MROs trained & examined prior to 8/1/01 have until 8/1/04 to complete refresher training)
 - 12 professional developmental hours on MRO functions
 - New technologies, interpretations, rule changes etc.
 - Must maintain documentation and provide upon request

- Verify lab results
- Inform employee of rights to request split specimen test within 72 hours
- Notify employer of positive test results
- Notify employer of safety concerns, if appropriate
- Process split test for employee
- Split tests are reported to employer
- Notify employer of retest request
- Maintain all necessary records
- MRO can not use alternative specimens (i.e. hair, blood etc

- Employee notification non negative
 - Notify employee of confirmed positive, adulterated, etc.
 - 3 attempts in 24 hours
 - If unable to contact, notify the DER
 - Results not discussed
 - The DER should instruct employee to contact MRO
 - If no contact within 24 hours, DER to leave message and notify the MRO
 - Verify positive test results without interview
 - » Employee refuses to discuss results with MRO
 - » After contacted by DER, Employee does not get in contact with MRO. Result in 72 hours
 - » No contact with donor in ten days after a good faith effort

- Verification process
 - Positive- marijuana, PCP, amphetamine, cocaine and opiates
 - Burden of proof is on the employee
 - Positive opiate <15,000 ng/ml
 - Burden of proof is on the MRO
 - Positive opiate 6-AM positive result
 - Adulteration or substitution
 - Burden of proof on the employee
 - Employee must demonstrate how the test results could be legitimately through physiological means
 - Physical examination within 5 days
 - Physician must be acceptable to the MRO

Medical Review Officer (continued)

Verified test results

- Negative:no action
- Negative dilute:employer may retest (be consistent)
- Positive: rule violation
- Positive dilute: rule violation
- Test refusal: rule violation
- Insufficient volume (medical explanation): cancelled
- Insufficient volume (no med explanation): test refusal
- Insufficient volume (long term disability): Negative
- Fatal flaw rejected for testing: cancelled
- Fatal flaw (pre-employment/rtn to duty): cancelled, retake

Medical Review Officer (continued)

- Verified Test results continued
 - Invalid result (medical explanation): cancelled
 - Invalid result (no medical explanation): cancelled and retest under direct observation
 - Primary positive/split fails to reconfirm: cancelled
 - Primary adulterated/substituted, split fails to reconfirm adulteration or substitution: cancelled
 - Primary positive/ adulterated/substituted and split unavailable or invalid: cancelled: retest under direct observation
 - Primary positive, split fails to reconfirm but is adulterated: test primary for adulteration

Medical Review Officer (continued)

Reporting Results

- Signed or stamped photocopy of Copy 2 of the custody and control form or...
- Written report for each result within 2 days of verification
 - Employee name
 - Specimen ID# and donor ID#
 - Reason for the test
 - Date of the collection
 - Result of test
 - Date the result was verified
 - Which drug was found
 - Reason for cancellation
 - Reason for a refusal (adulteration)

How to Audit your MRO

- ☐ Does the MRO have the appropriate credentials?
- □ Does the MRO have a copy of the MRO Guidelines?
- □ Are all negative results reviewed by the MRO or his/her designated staff
- ☐ If designated staff does the MRO review are 5% of the tests reviewed personally by the MRO to verify accuracy?

How to Audit your MRO

- □ Does the MRO use a script to ensure all information and disclosure is given to the donor during the interview?
- □ Does the MRO interview each donor with a nonnegative or questionable result?
- □ Does the MRO make at least 3 attempts in 24 hours to contact a donor?
- ☐ Does the MRO then notify the DER?
- □ Does the MRO understand the time frames for a non-contact positive result?

How to Audit your MRO

- □ Does the MRO inform the donor he/she has 72 hours to request the split sample test?
- □ Does the MRO notify the DER if a test must be retaken and under what circumstances?
- □ Does the MRO understand the new procedures for dealing with adulterated, diluted and unsuitable specimens?
- Does the MRO report results in a confidential manner

Substance Abuse Professional (SAP)

- Licensed physician
- Licensed or certified
 - Psychologist
 - Social Worker
 - Employee Assistance Professional
 - Addiction counselor certified
 - National Association of Alcoholism and Drug Abuse Counselors Certification Commission
 - International Certification Reciprocity Consortium

Substance Abuse Professional (SAP)

- Knowledge of and clinical experience in diagnosis and treatment of drug and alcohol related disorders
- Passed the SAP exam
- No conflicts of interest or financial interest in referrals
- Their goal is to protect the public and employer
- Not a cookie cutter program, must be individualized

SAP Responsibilities

- Evaluate type and amount of assistance needed by employee
- Determine if employee successfully completed recommended treatment
 - Confer with treatment professionals
 - Conduct face to face interview
 - Provide a written report to the DER
 - Specific guidelines for reports are in 40.311
- Determines when employee is ready to return-to-work and follow-up testing duration and frequency
- Referrals are required for all positive tests

How to audit your SAP

- ☐ Does your SAP have the appropriate credentials?
- ☐ Is the SAP familiar with the new part 40 guidelines?
- ☐ Does the SAP have a copy of the regulations?
- ☐ Are all individuals who have a positive result or refuse to test referred to a SAP?
- ☐ Are all applicants that test positive or refuse a preemployment test given the name of a SAP?

How to audit your SAP

- □ Does the SAP conduct a face to face evaluation with the donor?
 □ Does the SAP always recommend some assistance
- Does the SAP always recommend some assistance, either treatment or education?
- □ Does the SAP evaluate if an employee successfully complied with the recommended assistance?
- ☐ Does the SAP provide a written report to the you?
- □ Does the SAP establish the appropriate time for a return to duty test?
- □ Does the SAP recommend the duration and frequency of the follow-up tests?

How to audit your SAP

□ Does the SAP have a conflict of interest with the treatment or education provider?

C/TPA

- Transit systems are responsible for the integrity of the drug and alcohol program
- A Consortium/Third Party Administrator may perform some tasks on behalf of the employer
 - May act as an intermediary in the transmission of testing information
 - Must ensure that transmissions meet the requirements that would apply to the service agent
 - May operate random testing programs
 - May assist with laboratory and collection sites
 - May not randomly select for follow-up testing

C/TPA

- May receive and receive all drug and alcohol test results (except positive alcohol test results)
- C/TPA must ensure that if acting as an intermediary in transmitting information it must be in the appropriate timeframes
- Must ensure that employer's records are available within 2 days or request
- On request of employer, must transfer immediately all records pertaining to the employer and its employees.
- Must notify employers if C/TPA is going out of business, merging or selling the organization

C/TPA

- C/TPA may offer MRO services
- MRO services must be independent of C/TPA services.
- May not act as an intermediary in the transmission of alcohol test result of 0.02 or higher
- May not act as an intermediary of SAP reports

Auditing your C/TPA

- □ Does the C/TPA have the latest regulations and guidelines?
- Does the C/TPA share this information with the Service agents?
- ☐ Does the C/TPA keep you updated with any changes?
- ☐ Does the C/TPA have a system of maintaining quality of the service agents they recommend?

Auditing your C/TPA

- □ Do they help you respond to cancelled tests due to collection errors?
- □ Does the C/TPA belong to any professional organizations? Do they go to meetings?
- ☐ Are they supplying the correct CCFs?
- ☐ Will they supply you with non-federal CCFs?

Subcontractor

- "Stand in the Shoes" of the FTA recipients
- Contractual language regarding compliance
- Contracted taxi companies
- Must have Drug and Alcohol Testing Program
- Must maintain all records in a secure location separate from personnel files
- Policy and Procedures in place
- FTA recipient monitors for compliance

Employee's Records

- Drug Test result
- Employer copy of Custody and Control Form
- Copy of Employee Policy and Procedure signature of receipt form
- Employee pre-employment acknowledgment
- Previous employers' D&A records
- Post accident/Reasonable Cause report
- SAP information
- Training records

Five Year Requirement

- Positive Drug test results
- Alcohol test results greater than 0.02
- Chain of Custody Form
- Documentation of test results
- Employee dispute
- Employee referral to SAP
- Return-To-Work/Follow-up testing
- MIS Reports

Two Year Requirement

- Random Selection process
- Reasonable Suspicion Documentation
- Post Accident Testing documentation
- MRO documents verifying existence of medical explanation for insufficient volume
- Education and training for safety-sensitive employees and supervisor.

One Year Requirement

- Negative test results
- Alcohol results of less than 0.02
- Alcohol test forms with results
- Employer's copy of the USDOT Custody and Control Form

Self Audit

- ☐ Review your procedures for all testing events
- Review your paper-trails and accompanying documentation
- ☐ Graph the times and days of your random tests
- □ Be sure your MRO is sending signed (or stamped for negatives) complete results for each test which include:
 - □Employee's full name as indicated on the CCF
 - □ Specimen ID number for the CCF
 - ☐ Reason for the test as indicated on the CCF

Self Audit

- □ Date of the collection
- □Result of the test
- ☐ The date the result was verified by the MRO
- □ For verified positive tests, the drug metabolite(s) for which the test was positive
- ☐ For cancelled tests, reason for the cancellation
- ☐ For refusals to test, the reason for the refusal (name of the adulterant)
- ■No drug quantitative values

Self Audit

- □ Be sure to review your CCF to ensure that:
 □ The employer's name (your name) is in the appropriate space on the upper left hand corner of
 - the CCF
 - □Also the employer's address, phone and fax number is required in the same area.
 - ☐ The MRO's name, address, fax and phone number must appear in the appropriate section
 - ☐ The C/TPA may have their name on the CCF

Express

Analytical Laboratory

www.expressanalytical.com

Federal Drug Testing Custody and Control Form

3405 7th Avenue • Suite 104 • Marion, IA • 52302	III I NII III I I I I I I I I I I I I I
319-377-0500 Phone • 319-377-0300 Fax SPECIMEN ID NC	F-115/44
STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE	B. MRO Name, Address, Phone and Fax No.
A. Employer Name, Address, I.D. No. Provision Compliance Phy 333-499-1473	
1220 Raymwood Rd., Boulder, CO 80303	Or. J.R. Baher, MRO I Innwood Clarte Sta 202
Printings A Por Track	Little Rock, AR 72211
maphyan ABC Truck 113	\$1 - 25 11 Ph: 866 061 0633 Pay: 501 061 2624
and the control of th	e desir de la constante de la
C. Donor SSN or Employee I.D. No. 1入3・45-67ら	.5
	Reasonable Suspicion/Cause Post Accident
	☐ Other (specify)
	THC & COC Only Other (specify)
F. Collection Site Address:	· 128 /
Procision Compliance	Collector Phone No. 303 450 1473
1.20 Bavenwood Rd	
Heatlder, CC) SICKS	Collector Fax No
STEP 2: COMPLETED BY COLLECTOR	
	ecimen Collection:
	Split Single None Provided (Enter Remark) Observed (Enter Remark)
REMARKS	
STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor is TEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLE	Initials seal(s), Donor completes STEP 5 on Copy 2 (MHO Copy)
	on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in
accordance With applicable Federal requirements.	CDECIMEN POTTI E(C) DEL EACED TO
A 11 12 12 17 17 17 17 17 17 17 17 17 17 17 17 17	AM) SPECIMEN BOTTLE(S) RELEASED TO.
Signature of Collection Time of Collection	
(PRINT) Collegtor's Name (First, MI, Last) Date (Mo./Day/Yr.)	Name of Delivery Service Transferring Specimen to Lab
RECEIVED AT LAB:	Primary Specimen SPECIMEN BOTTLE(S) RELEASED TO:
X	Bottle Seal Intact
Signature of Accessioner	□Yes
(PRINT) Accessioner's Name (First, MI, Last) Date (Mo/Day/Yr.)	LJNo, Enter Remark Below
STEP 5: COMPLETED BY DONOR	
I certify that I provided my urine specimen to the collector; that I have not	adulterated it in any manner; each specimen bottle used was sealed with a tamper-
evident seal in my presence; and that the information provided on this form	m and on the label affixed to each specimen bottle is correct.
X Signature of Donor	(PRINT) Donor's Name (First, MI, Last) Date (Mo. / Day / Yr.)
Signature of Donor	(PRINT) Donor's Name (First, MI, Last) Date (Mo./ Day / Yr.)
Daytime Phone No. (2)2) 333-444 Fevening Phone	Mio Dav Yr.
Should the results of the laboratory tests for the specimen identified by thi	is form be confirmed positive, the Medical Review Officer will contact you to ask
about prescriptions and over-the-counter medications you may have taker	 Therefore, you may want to make a list of those medications for your own records.
PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY	er on a separate piece of paper or on the back of your copy (Copy 5). —DO NOT OF THE FORM, TAKE COPY 5 WITH YOU.
STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECI	
In accordance with applicable Federal requirements, my determination	10 AN 1964 NO 10 N
LINEGATIVE POSITIVE TEST CANCELLED THE	EFUSAL TO TEST BECAUSE:
L_ DILUTE	ADULTERATED I I SUBSTITUTED
REMARKS	
X	<u> </u>
Signature of Medical Review Officer	(PRINT) Medical Review Officer's Name (First, MI, Last) Date (No /Day/Yr.)
STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN	N
In accordance with applicable Federal requirements, my determination	ion/verification for the split specimen (if tested) is:
☐ RECONFIRMED ☐ FAILED TO RECONFIRM - REASON	
16.0	
Signature of Medical Review Officer	(PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.)

Wrap Up

Questions and Answers

Good Job!



Good Job!